Worldwide Regulatory Affairs
Pfizer Inc.
50 Pequot Avenue
New London, CT 06320

Global Research & Development

June 16, 2008

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Draft FDA Guidance "*Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007 [Docket No. FDA-2008-D-0224]*"[1]

Dear Sir or Madam,

Thank you for the opportunity to comment on the ***Draft FDA Guidance "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007***, which was announced in a *Federal Register* notice April 18, 2008 (Docket No.2008-D-0224).

Our comments are attached.

Please do not hesitate to contact the undersigned if there are any questions regarding the above comments, or if further clarification or information is desired.

Sincerely,

Ron Guido /p.1.p

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[1] 73 FR 21142 (Date of 18 April 2008, Federal Register Docket No. 2008-D-0224).

Pfizer respectfully submits the following comments to the Agency for consideration:

General Comments:
Pfizer feels that the 3674 should be included with safety reports since a great majority of these reports are associated with clinical studies
Specific guidance is requested if the NCT number is pending and not yet available on ClinTrials.gov, can a sponsor still check box C? If so, what does industry identify as the NCT number or is this left blank?
Is it necessary to include the second page of the 3674 form with each submission given that it only includes Instructions for Completion of the form and the Paperwork Reduction Act Statement?